

REMARKS

Pending Claims:

Claims 1 to 8 and 10 are pending. Claims 6 to 8 and 10 have been withdrawn from consideration by the Examiner.

Rejections under 35 U.S.C. § 103:

Claims 1 to 5 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,770,149 to Raible in view of U.S. Patent Application Publication No. 2002/0057990 to Ghelli et al. Applicants respectfully traverse this rejection of the claims.

Claim 1 is the only independent claim. Claim 1 requires at least two features not disclosed in Raible. Specifically, claim 1 requires: 1) a venous blood reservoir, heat exchanger, oxygenation apparatus, arterial blood filter and pulsating pump which are integrated into a single monolithic assembly; and 2) that the pulsating pump have an inlet connected to receive blood from the outlet of the heat exchanger. With respect to claim 1 the Examiner states that Raible teaches a venous blood reservoir, heat exchanger, pump, oxygenation apparatus, and arterial blood filter integrated into a single monolithic assembly. The Examiner also states that Raible teaches a pulsating pump. The Examiner then states that Raible does not “teach the pulsating pump being the pump connected to receive blood from the outlet of the heat exchanger”. This statement seems to imply that the Examiner believes Raible contains some disclosure or teaching of a pump connected to receive blood from the outlet of the heat exchanger. It does not.

Applicants submit the Examiner’s description of Raible is inaccurate or at least incomplete. Applicants agree that Raible teaches an integrated unit which includes a venous blood reservoir, heat exchanger, pump, oxygenation apparatus, and blood filter. However, Raible teaches that the pump which is included within

the integrated unit is a centrifugal pump. Raible also teaches the use of a second non-integrated pump which can be used to bypass the integrated pump should it malfunction. Specifically, Raible provides a recirculation/emergency port 150 on the integrated unit. Should the integrated pump malfunction the blood return tube which had been attached to the blood inlet port 28 is connected to the recirculation/emergency port 150 and a second, separate pump, which can be either a peristaltic pump or a centrifugal pump, may be connected to or mounted on the blood return tube to provide the pumping force necessary to propel the blood through the system (Raible, col. 9, lines 32-56, FIG. 3). When connected in this manner the integrated pump is bypassed since the outlet of the second pump is connected to provide blood from the patient directly to the inlet of the heat exchanger (see Raible, FIG. 3). Raible never teaches or suggests that the integrated pump be anything other than a centrifugal pump. Further, Raible does not teach nor disclose that either the integrated pump or the second pump have its inlet connected to receive blood from the outlet of the heat exchanger.

The Examiner describes Ghelli as teaching “a device for treating blood in an extracorporeal circuit having a venous blood reservoir, a heat exchanger, a pump, an oxygenation apparatus, and an arterial blood filter (Fig. 7, paragraphs 1-3, 14, 24-27).” The Examiner further states that “Ghelli teaches the integration of these components into a single monolithic assembly to save space in the vicinity of the operating field (Fig. 7 and paragraphs 2-3, 24-27).” Applicants respectfully submit that the Examiner’s characterization of Ghelli in this respect is incorrect. FIG. 7 in Ghelli discloses a pumping unit integrated into an assembly with an oxygenator and a heat exchanger. There is no disclosure nor suggestion of the integration of a reservoir and arterial filter into the device disclosed in FIG. 7.

The Examiner further states that Ghelli teaches a pulsating pump receiving blood from the outlet of a heat exchanger. Therefore, the Examiner concludes that

it would have been obvious to one of ordinary skill in the art to modify Raible to include a pulsating pump receiving blood from the outlet of the heat exchanger, as taught by Ghelli. Applicants respectfully disagree with the Examiner's conclusion. First, the peristaltic pump described by Raible is a separate pump which does not form a part of the integrated system disclosed by Raible. That separate pump is connected and used only in emergency situations where the centrifugal blood pump of the integrated system fails. In the event of such pump failure Raible discloses a method of bypassing the integrated centrifugal pump and connecting this second or emergency peristaltic pump in or on a blood return tube which is connected to a recirculation/emergency port 150. There would be no reason for a person of skill in the art to connect this separate peristaltic pump to the outlet of the heat exchanger disclosed in Raible. As a matter of fact such a connection to the separate peristaltic pump could not be made without substantial modification to the integrated system disclosed by Raible. Even if such a connection were made the peristaltic pump would not be integrated into the monolithic assembly as required by claim 1.

Further, a person of skill in the art would have no reason to replace the integrated centrifugal pump of Raible with a pulsating pump such as disclosed in Ghelli and then to make the further substantial modification of connecting the inlet of that pulsating pump to the outlet of the heat exchanger. Such a modification would require substantial changes to the integrated system disclosed by Raible. A person of skill in the art would have no reason to make those changes, especially since they would eliminate the benefit of the recirculation/emergency port 150 in enabling the integrated pump to be bypassed quickly upon pump failure by connecting a second non-integrated pump to the inlet of the heat exchanger.

The Examiner states that it is well known in the art to vary the order in which the components of a device for extracorporeal blood treatment are connected and

to include pumps at various points between the components of the system as needed to keep the blood flowing. Applicants submit, however, that such statements of general knowledge by the Examiner, even if true, provide no basis or reason why a person of skill in the art would modify Raible in the particular manner required by claim 1. In other words, the general knowledge of a person of skill in the art does not render the claims obvious unless that general knowledge is such that would reasonably result in the person of skill in the art making the specific modifications to the prior art that are required by the claims. For the reasons set forth above there is no reason a person of skill in the art would combine the cited references in the manner required by claim 1.

In response to the arguments previously submitted by Applicants the Examiner states that "Applicant's specification does not teach that a pulsating pump serves any stated purpose or solves any particular problem." The Examiner further states that "Applicant's specification does not disclose that blood flow through the heat exchanger and then the pump, rather that the pump first and then the heat exchanger, serves any stated purpose or solves any particular problem." Applicants submit that the Examiner is incorrectly focusing on only isolated portions of the claim rather than the entirety of the claim. Applicant's invention comprises all of the components set forth in claim 1 which are integrated into a single monolithic assembly in the manner required by claim 1. As to the claimed device Applicant's specification provides ample description of the purpose of the invention and the problems which are solved (see for example, specification, page 2, lines 2-12).

Claim 1 is allowable for the reasons set forth above. Claims 2 – 5 depend from claim 1 and add further limitations. Claims 2 – 5 are thus allowable for at least the same reasons as set forth above with respect to claim 1.

Response
Applicants: Edgardo Costa Maianti et al.
Serial No.: 10/614,722

Attorney Docket: DID1044US

Conclusion

In view of Applicants' remarks, the claims are believed to be in condition for allowance. Reconsideration, withdrawal of the rejections, and passage of the case to issue are respectfully requested.

If any additional fees are due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 16-2312. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our deposit account.

Respectfully submitted,

Date: 2/12/08

By


Customer No. 009561

Terry L. Wiles (29,989)

Patrick J. O'Connell (33,984)

POPOVICH, WILES & O'CONNELL, P.A.

650 Third Avenue South, Suite 600

Minneapolis, MN 55402-1911

Telephone: (612) 334-8989

Attorneys for Applicants